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August 14, 2003

Marianne L. Horinko, Acting Adminstrator
U.S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Subject: Comments on the HPV Test Plan for 4-Nitrophenol, or PNP

Dear Administrator Horinko:

The following comments on Solutia's test plan for the chemical 4-Nitrophenol, also known as para-Nitrophenol or PNP, are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

Solutia, Inc. submitted its test plan on April 17, 2003 for the chemical PNP (CAS No. 100-02-7), which is manufactured in the U.S. by Solutia at a single site. PNP is then sold to a limited number of customers for the express purpose of full chemical conversion into other industrial chemicals used as dyes/pigments, pharmaceuticals, analgesics, and adhesives. Solutia has submitted a comprehensive analysis of PNP by compiling substantial amounts of existing data from a variety of sources. In addition, this company considers potential exposure to PNP and appropriately concludes that very limited occupational or environmental exposure is expected to occur. When considering the toxicity of a chemical, these approaches demonstrate a thoughtful analysis by Solutia. Information from existing data for physicochemical properties, environmental fate, and human and environmental effects of PNP have led Solutia to conclude that no additional testing is necessary under the HPV Challenge program.

We commend Solutia's efforts in drawing on all available information from a myriad of sources to meet the SIDS endpoints for the chemical PNP. This approach is consistent with the EPA's stated goals of maximizing the use of existing data in order to limit additional animal testing. At this time we would like to point out that although no developmental toxicity data for PNP was included in the test plan, results from the two-generation rat reproductive toxicity study show no evidence of developmental toxicity. Data from individual pup weights and viability at birth, day 4, day 7, day 14 and at weaning provide strong evidence that PNP does not pose a developmental hazard.

However, if EPA wishes Solutia to further investigate potential developmental toxicity, this would be the perfect opportunity for the EPA and Solutia to agree to conduct the rodent embryonic stem cell test (EST), an *in vitro* embryotoxicity test method validated by ECVAM in 2002. Data from the EST together with the reproductive toxicity data could be used to address this SIDS endpoint. The Institute for In Vitro Sciences, Inc. in Gaithersburg, MD is currently offering the EST test to clients in the U.S. and elsewhere. We sincerely hope that Solutia will take a leadership role in pursing the EST test to meet the developmental toxicity endpoint in the HPV program, thereby sparing large numbers of animals. Thank you for your attention to these comments. I may be reached at 202-686-2210, ext. 327, or via e-mail at meven@pcrm.org.

Sincerely,

Megha Even, M.S.
Research Analyst

Chad B. Sandusky, Ph.D.
Director of Research